

**REMARKS**

**I. Amendment to the Claims:**

Claims 38-42, 44, 46-57, 89, 99, and 100 are pending and under examination in the instant application.

By this paper claim 46 has been amended to alter its dependency. No new matter is added by this amendment.

**II. Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description:**

Claims 38-42, 44-57, 89 and 99-100 stand rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to comply with the written description requirement (*see*, Office Action, pages 4-5). The Office Action asserts that claims 38 and 89 recite new matter because there is allegedly no support for a method comprising monitoring the level of a marker in the patient's blood or serum and monitoring the level of newly produced T cells by monitoring T cell receptor excision circles or "TRECs". (*see*, Office Action, page 3).

Applicants respectfully traverse this rejection.

Firstly, Applicants stand by, and re-assert, the arguments made previously in the amendment of May 30, 2008 regarding support for combination methods comprising both monitoring the level of a marker in the patient's blood or serum and monitoring the level of TRECs.

In addition, Applicants wish to direct the Examiner's attention to page 12, lines 11-18, of the application as filed, which states:

*In one embodiment, the diagnosis is accomplished by measuring the amount of thymic induced factors in a blood sample of the patient before and after initiation of inhibition. In yet another embodiment, the invention is used to identify previously unidentified thymic factors. In another embodiment, the diagnosis is accomplished by measuring thymic activity. **In addition to the above**, this will be achieved by determining levels of newly produced T cells identified by the presence in these cells of small circles of DNA termed T cell receptor excision circles (TREC's). (emphasis added).*

The above cited section of the specification as filed provides further support for a method for determining the susceptibility of a thymus to reactivation in a patient comprising monitoring the level in the patient's blood or serum of a marker associated with activation of the thymus **and** monitoring the level in the patient's blood of newly produced T cells by monitoring T Cell Receptor Excision Circles (TRECs), as recited in the present claims.

In view of the foregoing, Applicants respectfully submit that the grounds for this rejection have been overcome. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

## **II. Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 46-49 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In particular, the Office Action points out that claim 46 depends from claim 45, which has been cancelled.

By this paper, claim 46 has been amended to depend from 44, such that the grounds for this rejection have been overcome. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

## **III. Rejections Under 35 U.S.C. § 102**

Claims 46-47, 57, and 100 stand rejected under 35 U.S.C. § 102. Applicants respectfully traverse the rejections, as follows:

### **(i) *Boyd et al.* US 2002/0136704.**

Claims 46-47, 57, and 100 are rejected under 35 U.S.C. § 102(b) as anticipated by *Boyd et al.* US 2002/0136704 (hereinafter "Boyd 2002"). Boyd 2002 is the grandparent of the present application, and the present application claims priority to Boyd 2002.

The Office Action states "the disclosure [of Boyd 2002] pertaining to the pharmaceuticals administered ... cannot support instant dependant claims 46-47 and 100" and that "the disclosure of [Boyd 2002] pertaining to the markers measured cannot support instant dependant claim 57. For example, at least CXCL12 [and] CXCL19 are not supported." The Office Action does not go

on to say how the above statements support the assertion that claims 46-47, 57, and 100 are anticipated by Boyd 2002.

Applicants respectfully aver that the above rejection is flawed and does not constitute a proper or comprehensible rejection of the claims under 35 U.S.C. § 102(b). In order to anticipate a claim, a reference must teach each and every element of the claim (See § MPEP 2131). The Office Action fails to state that Boyd 2002 teaches every element of the present claims. In fact, the Office Action states the contrary – it states that Boyd 2002 fails to support the present claims. Thus the Office Action *fails* to make a proper rejection of the claims under 35 U.S.C. § 102(b).

The Office Action appears to propose two conflicting arguments. The Office Action appears to suggest that Boyd 2002 does not support the present claims and is thus prior art. However, the Office Action then appears to suggest that present claims are anticipated by Boyd 2002. These two propositions contradict one another. On the one hand, if Boyd 2002 does not support the present claims, then it cannot teach all of the elements of the present claims and cannot anticipate the claims under 35 U.S.C. § 102. On the other hand, if Boyd does teach every element of the rejected claims, as is necessary to support a rejection under 35 U.S.C. § 102, then the present claims are entitled to the filing date of Boyd 2002, and thus Boyd 2002 cannot constitute prior art.

In the event that an Office Action containing a proper rejection of the claims as anticipated by Boyd 2002 is issued by the Office, Applicants will at that time address the merits of such a rejection.

**(ii) Boyd *et al.* US 2003/0017153.**

Claims 46-47, 57, and 100 are rejected under 35 U.S.C. § 102(a) or (e) as anticipated by Boyd *et al.* US 2003/0017153 (hereinafter “Boyd 2003”). Boyd 2003 is the great grandparent of the present application, and the present application claims priority to Boyd 2003.

The Office Action states “the disclosure [of Boyd 2003] pertaining to the pharmaceuticals administered ... cannot support instant dependant claims 46-47 and 100” and that “the disclosure [of Boyd 2002] of the markers measured cannot support instant dependant claim 57. For example, at least CXCL12 [and] CXCL19 are not supported.” The Office Action does not go on

to say how the above statements support the assertion that claims 46-47, 57, and 100 are anticipated by Boyd 2002.

The above rejection is flawed for the same reasons that the rejection of the claims as anticipated by Boyd 2002 is flawed, as described above, and accordingly, the rejection of the claims as anticipated by Boyd 2003 is not proper.

In the event that an Office Action containing a proper rejection of the claims as anticipated by Boyd 2003 is issued by the Office, Applicants will at that time address the merits of such a rejection.

**(iii) Markush Group**

On page 6 of the Office Action, in the section entitled “New Rejections Under 35 U.S.C. 102”, the Office Action states: “[t]he number of pharmaceuticals/markers recited in each of claims 46-47 and 57 is excessively long for the examiner to search each Markush group member. In order to overcome the rejection, Applicants must cancel all Markush group members in the instant claims which lack support in the earlier documents.”

The meaning of the above rejection is unclear. This does not constitute a proper rejection of the claims under 35 U.S.C. § 102 or a proper requirement for an election of species.

In the event that the Office issues a proper requirement for an election of species, Applicants will address the Examiner’s concern at that point.

In view of the foregoing, Applicants submit that the Office Action fails to make out a valid rejection of the claims under 35 U.S.C. § 102. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

**CONCLUSION**

Upon entry of the instant amendment, claims 38-42, 44, 46-57, 89, 99, and 100 will remain pending in this application.

Applicants petition for a one-month extension of time to respond to the outstanding Action. Please charge the fee for this one-month extension to our Deposit Account No. 08-0219. No additional fees are believed to be due in connection with this filing; however, if any fees are due, please charge such fees to our Deposit Account No. 08-0219.

If a telephone interview would advance prosecution of the application, the Examiner is encouraged to telephone the undersigned at the telephone number given below.

Respectfully submitted,

Dated: December 12, 2008

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